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(54) [Title of The Invention] Apparatus for placement in lumen

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## I. Title of The Invention: Apparatus for placement in lumen

## II. Scope of Claim for Patent

1. Apparatus for placement in lumen characterized by comprising a cylinder which is cut axially on the surface consisting of shape memory alloy narrowing the diameter by spirally winding the shape at the temperature under a transition point of the shape memory alloy.
2. Apparatus for placement in lumen of claim 1 wherein a cylinder has a concave shape with a shorter diameter in the middle region compared to the end regions.
3. Apparatus for placement in lumen of claim 1 wherein one or more than one cylinders made of flexible material are coupled axially.
4. Apparatus for placement in lumen as claimed in any one of claim 1 to claim 3 wherein transition temperature of shape memory alloy is slightly less than 37 degree Celsius.
5. Apparatus for placement in lumen as claimed in any one of claim 1 to claim 3 wherein a surface of cylinder is coated with flexible material.
6. Apparatus for placement in lumen of claim 5 wherein flexible material used is polyester woven fabric or mesh fabric.
7. Apparatus for placement in lumen of claim 5 wherein flexible material used is porous polytetrafluoroethylene film.
8. Apparatus for placement in lumen of claim 5 wherein flexible material used is silicon, polyurethane, poly (meta) acrylic ester coat.
9. Apparatus for placement in lumen as claimed in any one of claim 1 to claim 8 wherein a surface of cylinder is coated with blood anticoagulation agent"

## III Detailed Description of The Invention

[Industrial applicability] This invention relates to a medical device which is placed inside a lumen for treating a lesion occurred in a lumen such as blood vessel or bronchus.

[Prior Art] As is generally known, a living body is comprising many lumens with internal organs. In these organs, stenosis, rupture and abnormal dilatation occur in some cases causing various diseases. As treatments for these diseases, surgical treatments have hitherto been conducted in the lesions.

[Problems To Be Solved By The Invention]

Since invasiveness is large in a surgical treatment and the risk in surgery is considered to be high in some patients, there are some cases where doctors could not proceed to a surgical treatment or patients didn't recover after surgeries.

It is therefore one object of the present invention to provide apparatus with which said lesion in lumens and organs are treated easily without conducting surgical treatments.

[Means For Solving The Problem]

Apparatus in this invention is comprising a cylinder which is cut axially on the surface consisting of shape memory alloy and narrows the diameter by spirally winding the shape at the temperature under a transition point of the shape memory alloy. More than 10 alloys, such as Ni - Ti, are known to be said shape memory alloys so far.

[Working action]

Apparatus in this invention is used as follows:

Selecting apparatus with the almost same sized diameter or slightly larger diameter as the lumen, insert the apparatus into a lumen using a catheter or the like keeping the temperature of the apparatus below a transition point and restore cylindrical shape by heating a temperature above the transition point of the shape memory alloy at the lesion region. Thus, stenosis in a lumen is dilated in the lesion to be recovered. For a lesion with ruptures or an abnormal dilation, the apparatus is attached closely to the inner wall of the lumen to protect the lesion.

Since shape memory alloy has a characteristics of flexibility at a temperature below a transition point in this invention, it is easy to wind the material spirally at the temperature. Since spiral winding makes the diameter smaller compared to the original size of cylinder, it can be inserted easily through a lumen.

It is desirable to utilize a body temperature to heat shape memory alloy above the transition point. Thus, it restores the original size of the cylinder since body temperature heats it up to the transition point automatically, when alloy, which has a transition temperature slightly below 37 degree Celsius, is taken out from a catheter at the lesion region after the member is delivered to the region using a catheter or the like being kept cool. Therefore it is desirable to have a transition temperature slightly below 37 degree Celsius. If a transition temperature is over 37 degree Celsius, the alloy should be heated using a high frequency induction heating device or warm physiological saline.

[Description Of Preferred Embodiments ]

Hereafter, the invention is described more particularly by way of preferred embodiments shown in the drawings.

FIG. 1 to FIG. 4 are an example of this invention.

FIG. 1 shows a state before the alloy is wound spirally, while FIG. 2 shows a state when the alloy has been wound spirally. As you see, cylinder 1 features a cut 2 on the surface axially to be opened at this cut and to be wound spirally at a temperature below the transit temperature before insertion as shown in FIG. 2.

FIG. 3 shows an example where apparatus of this invention is used for stenosis in a lumen. First apparatus of this invention 1 is inserted to a region near a lesion 6 in a lumen 5 delivering it through a catheter 3 using

forceps 4 (FIG. 3 A). In this stage, it is important to prevent transition of the state by injecting physiological saline solution (for a blood vessel) or air (for bronchus) continuously keeping inside the catheter in a temperature below a transition point. Then push the retaining forceps further to push out the end point to be stacked out the tip of the catheter to locate the apparatus 1 in the stenosis region 6 (FIG. 3 A). Since the apparatus 1 experiences transition of state after being heated in a body temperature to start recovering the original cylindrical shape, release the apparatus 1 from being hold by the forceps after the apparatus 1 is fixed in the stenosis region (FIG. 3 C). The apparatus 1 restores the original cylindrical shape eventually and it expands the stenosis to the same inner diameter as other regions (FIG. 3 D).

FIG. 4 shows an example where the apparatus of this invention is used for sealing a rupture 7 in a lumen. When the apparatus restores the original cylindrical shape, it attaches closely to the inner wall of the lumen and the ruptured region is shielded to be closed. In this case it is desirable to use apparatus whose outer diameter when restored is slightly larger than the inner diameter of the lumen.

FIG. 5 is an example where the apparatus of this invention is used to prevent abnormal dilation 8 in a lumen. By this way, the abnormal dilation 8 is prevented and the lumen is protected from being ruptured.

FIG. 6 and FIG. 7 are perspective views of apparatus the invention for the embodiments. The cylinder shown in FIG. 6 is shaped in the way that the diameter in the middle region is smaller than the ones in the end regions to be fixed easily on the stenosis. Fig. 7 shows a configuration where cylinders 9, 10, 11 and 12, made with shape memory alloy are coupled axially by flexible materials 13, 14 and 15. In this configuration, the pieces are bent in the middle regions to be inserted or placed in a lumen when the device is relatively long.

Although the shape memory alloy can be used in the state as is in the apparatus in this invention, the surface can be coated with a flexible material. The following flexible materials are indicated as examples: Woven fabric or mesh fabric made of polyesterfabric and coatings such as porous polytetrafluoroethylene, silicon, polyurethane, poly (meta) acrylic ester. Since these materials are excellent in compatibility with blood and fabrics, it is capable for the placements in lumens for a long period. It is also possible to coat blood anticoagulation agent such as heparin or urokinase on the surface of the shape memory alloy or the surface of the coating materials.

[Advantageous Effect of The Invention] it is desirable to use apparatus of this invention since treatment inside lumen can be carried out without invasive surgical treatments. Also, since a diameter of apparatus is reduced by winding spirally, it is easy to be inserted into a lumen. It restores the original cylindrical shape to work its functions by heating above the transit temperature with an easy operation. Particularly if shape memory alloy with a transit temperature slightly lower than 37 degree Celsius is chosen, it is very convenient to use since a transit is occurred automatically at a body temperature.

#### IV. [BRIEF DESCRIPTION OF THE DRAWINGS]

FIG. 1 and FIG. 2 show perspective views an example of apparatus of this invention. Fig. 1 shows a state before changing shape and FIG. 2 shows a state when it has been wound spirally.

FIG. 3 shows a partial cross section for an example where the embodiment indicated in Fig. 1 and FIG. 2 are used for stenosis in a lumen.

FIG. 4 shows a partial cross section for an example where the apparatus of this invention is used for sealing a rupture in a lumen.

FIG. 5 is an example where the apparatus of this invention is used to prevent abnormal dilation in a lumen. FIG. 6 and FIG. 7 are perspective views of apparatus the invention for the other embodiments.

The followings are the names for the symbols in the drawings.

- 1.....Cylinder
- 2.....Cut
- 5.....Lumen
- 6.....Stenosis region
- 7.....Rapture region
- 8.....Abnormal dilation

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